**DEPARTMENT OF HEALTH & HUMAN SERVICES** Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

March 20, 2015

Sunny Medical Device (Shenzhen) Co., Ltd.
Mr. James Qi Zhang
General Manager
56 Lehigh Aisle
Irvine, California 92612

Re: K140356
Trade/Device Name: Sunmed High Pressure Line
Regulation Number: 21 CFR 870.1200
Regulation Name: Diagnostic Intravascular Catheter
Regulatory Class: Class II
Product Code: DQO
Dated: February 2, 2015
Received: February 18, 2015

Dear Mr. Zhang,

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in

the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

# 2. Indications for Use Statement

**Indications for use**

510(k) Number (if known): K140356

Device Name: Sunmed™ High Pressure Line

Indications for Use:

The Sunmed™ High Pressure Line is used as a connecting line for injection of a contrast, saline or other diagnostic fluids (by connecting the female luer of high pressure with an angiographic syringe and connecting the male luer or rotating male luer of high pressure with the catheter) during coronary angiography procedures. This product is composed of female luer, male luer (including rotating male luer), and tubing and with or without caps.

| Prescription Use ✘ | AND/OR | Over-The-Counter Use _____ |
|---|---|---|
| (Part 21 CFR 801 Subpart D) | | (Part 21 CFR 801 Subpart C) |

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Concurrence of CDRH, Office of Device Evaluation (ODE)

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# 1. 510(k) Summary

1. Submitted by: Sunny Medical Device (Shenzhen) Co., Ltd.

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Irvine, CA 92612

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Contact: James Qi Zhang, General Manager

E-mail: jamesqizhang@gmail.com

Date: Nov. 18, 2013

2. Proposed Device:

Trade/Proprietary Name: Sunmed™ High Pressure Line

Common/Usual Name: Disposable High Pressure Line

Classification: II

Classification Name: Diagnostic intravascular catheter

Regulation Number: 870.1200

Product Code: DQO

3. Predicate Device:

| 510(K) Number | Trade or Proprietary or Model Name | Manufacturer |
|---|---|---|
| K071196 | Disposable High Pressure Injection Lines and without Rotating Adapters | Coeur Medical, a division of Coeur Inc. |
| K023591 | Ultra High Pressure Injector Lines | DeRoyal Industries, Inc. |

4. Device description

The Sunmed™ High Pressure Line is composed of female luer, male luer (including rotating male luer), and tubing and with or without caps.

The Sunmed™ High Pressure Line is used as a connecting line for injection of a contrast, saline or other diagnostic fluids (by connecting the female luer of high pressure with an angiographic syringe and connecting the male luer or rotating male luer of high pressure with the catheter) during coronary angiography procedures. This product is composed of female luer, male luer (including rotating male luer), and tubing and with or without caps.

The Sunmed™ High Pressure Line is single use and supplied sterile by Ethylene Oxide.

Package:
Material: Dupont Tyvek package for medical use.

5. Intended Use

The Sunmed™ High Pressure Line is used as a connecting line for injection of a contrast, saline or other diagnostic fluids (by connecting the female luer of high pressure with an angiographic syringe and connecting the male luer or rotating male luer of high pressure with the catheter) during coronary angiography procedures. This product is composed of female luer, male luer (including rotating male luer), and tubing and with or without caps.

6. Technological Comparison to Predicate Device

The technological characteristics of the subject device, The Sunmed™ High Pressure Line, are equivalent to Disposable High Pressure Injection Lines and without Rotating Adapters and Ultra High Pressure Injector Lines in terms of intended use, materials, fundamental scientific technology, operating principle, sterility assurance level, and method of sterilization.

7. Summary of the technological characteristics of our device compared to the predicate device:

The predicates were compared in the following areas and found to have identical technological characteristics and to be equivalent because they are the identical products.

Indications for Use
Material
Components
Technique (Components/Flexible/Packaging/Pressure )
Sterility
Biocompatibility

8. Summary of Non-Clinical Testing

The following tests were performed on the Sunmed™ High Pressure Line:

Biocompatibility Testing:
*Pyrogen Test*
*Acute Systemic Toxicity Test*
*Intracutaneous Reactivity Test*
*In Vitro Cytotoxicity Test*
*Skin sensitization Test (two kinds of solvent)*
*In Vitro Hemolysis Study( ASTM F756-08)*
Aging Testing
Bench Testing
Package Penetrate Testing
Asepsis Testing
EtO and ECH Residue Testing

9. Clinical Evaluation was not applicable.

10. Conclusions

Based on the information presented in this 510(k) premarket notification, the Sunmed™ High Pressure Line is considered substantially equivalent to the Disposable High Pressure Injection Lines with and without Rotating Adapters and Ultra High Pressure Injector Lines.